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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,307	10/26/2001	Michael R.S. Hill	P-8969.00	2140

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/039,307

Applicant(s)

HILL ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/26/01 (Initial Filing).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4.6</u>   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 17-27, and 30-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implant within the body amounts to inferential recitation of the body, which renders claims 17-20, 23-27, and 30-33, and there dependent claims, non-statutory. For example in claim 17, it is suggested the limitation the “electrode located in a region associate with nervous tissue in a patient’s body” be amended to the --electrode adapted to be located in a region associated with nervous tissue in a patient’s body-- to address the understood intent of the Applicant and avoid the 35 U.S.C. 101 rejection. Similar correction is required for claims 18-20, 23-27 and 30-33.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1, 2, 4-13, 15-18, 20-34 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (US 5199428). Obel et al. disclose an implantable electrical nerve stimulator/ pacemaker, the nerves being stimulated in the region of the thoracic vertebra T2 and the stimulation coordinated with the heart to provide resynchronization therapy (abstract; col. 1 @ 15-24; col. 3 @ 8-28 & 42-45; col. 3 @ 62 – col. 4 @ 26; col. 5 @ 25-64). Anti-tachycardia pacing may be incorporated (col. 9 @ 53 – col. 10 @ 2).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 3, 19, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Adams (US 57992187). As discussed in paragraph 4 of this action, Obel et al. disclose the claimed invention except for the driver circuit delivering high-voltage stimulation (claim 39), and the electrode located external to the patient's body (claims 3 and 19).

As to delivering high voltage stimulation, Adams teaches cardiac arrhythmia treatment using cardioversion/ defibrillation shock therapy for the purpose of converting dysrhythmia to normal sinus rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used high voltage stimulation in the Obel et al. system in order to offer a proven alternate treatment for arrhythmias so the dysrhythmia is effectively treated before the patient suffers any ill effects from the dysrhythmia (col. 3 @ 1-8).

As to the electrode being located external to the patient's body, Adams teaches pain suppression treatment using an electrode (100) located external to the patient's body at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient's body in the Obel et al. system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient's pain, apprehension and anxiety is controlled (abstract; col. 2 @ 48-55; col. 3 @ 1-8 & 45-48; col. 7 @ 11-24). It is noted both electrical and electromagnetic pain suppression systems are well known in the art, and absent any teaching of criticality or unexpected results merely changing the type of system from an electromagnetic system to an electrical system would be an obvious design choice.

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7. Claims 14, 35 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Sweeney et al. (US 6272377). As discussed in paragraph 4 of this action, Obel et al. disclose the claimed invention except for the electrode being located on an intrinsic cardiac ganglia (claims 14, 35) and providing a drug delivery device with agent (claim 40).

Sweeney et al. teach arrhythmia treatment using drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) for the purpose of preventing the development of an arrhythmia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) in the Obel et al. system in order to provide alternate proven means to prevent or reduce the consequences of the arrhythmia (abstract; col. 45 @ 61 – col. 5 @ 5; col. 8 @ 49-55).

### *Drawings*

8. The drawings are objected to because:
- In figure 2, the “Pacing/ High-Voltage Stimulation” box does not have a reference numeral, and
  - In figure 5, the reference numeral “500” is used twice to refer to two different steps.

***Specification***

9. The specification is objected to because:
- The Serial Numbers, Patent number needed to be supplied on pages 1 and 9 of the specification,
  - On page 10, line s 28 and 31, the reference numeral "213" is used twice to define two different elements, and
  - One page 14, line 1, reference numeral "(504)" is not found in figure 5.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frances P. Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached Monday through Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on (703) 308-5181.

The telephone number for facsimiles for regular communication and After Final communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

FPO  
9/9/04

Angela D. Sykes

ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
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